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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/729,668 | 12/05/2003 | Peter M. Bonutti | 2500DV2CN2DV3CN2 | 3159 |

7590 12/13/2005

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/729,668 | Applicant(s) BONUTTI, PETER M. | |
| | Examiner Michael Thaler | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-23, 25-79 and 81-101 is/are pending in the application.
- 4a) Of the above claim(s) 7, 9, 12, 14, 43-46 and 85-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 11, 13, 15-23, 25-42, 47-79, 81-84 and 89-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2005 has been entered.

Claims 7, 9, 12, 14, 43-46 and 85-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on August 18, 2004.

Claims 1, 8, 10, 11, 13, 15-19, 27-30, 38-42, 47-51, 53-55, 59-62, 64-70, 72 and 73 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon discloses the steps of providing an apparatus (e.g. 10, 57, 57a in figure 4) having a distal portion and an expandable bladder 57 coupled to the distal portion, positioning the expandable bladder 57 between adjacent vertebrae (noting the term "inter-vertebral space" in col. 9, lines 62-66) and expanding the expandable bladder to spread the adjacent vertebrae apart (The expansion of the

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expandable body 57 within the inter-vertebral space creates space for viewing as described in col. 9, lines 66-70. The creation of this space between the vertebrae inherently spreads the adjacent vertebrae apart. Further, the outer surfaces of the expandable bladder 57 are configured to engage and spread the adjacent vertebrae apart for the same reason.) Alternatively, it would have been obvious that the creation of this space between the vertebrae spreads the adjacent vertebrae apart since the space that is created is located between the vertebrae. As to claim 8, bladder 57 is wedge-shaped as seen in figure 4. As to claim 49, Sheldon discloses the step of introducing the retractor through a passage of a cannula 5 (col. 3, lines 9-13).

Claims 2-5, 20-23, 25, 26, 31-37, 52, 63, 71, 74, 78, 79, 82-84 and 89-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745). Sheldon fails to specifically indicate that the herniated disc described from col. 1, line 51 to col. 2, line 7 is operated on. However, it is old and well known in this art to remove an intervertebral disc when it is diagnosed as being herniated in order to obtain the advantage of relieving pain. It would have been obvious to remove the herniated disc during the Sheldon procedure so that this procedure too would have this advantage. As to claim 71,

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Sheldon fails to disclose applying a vacuum to deflate the bladder 57. However, it is old and well known in this art to deflate a balloon by applying a vacuum to the balloon in order to obtain the advantage of quickly deflating it. It would have been obvious to use a vacuum to deflate the Sheldon bladder 57 so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 56-58, 75-77 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745) in view of McDaniel (4,501,266). Sheldon fails to disclose using the device in a knee. However, Sheldon does teach that the device may be used in areas of the body other than the spine (col. 2, lines 8-9). Further, McDaniel teaches that the knee is an area of the body that requires surgical intervention and distraction. It would have been obvious to use the Sheldon device in the knee for this reason.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 8, 10, 11, 13, 15-23, 25-42, 47-79, 81-84 and 89-101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,017,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor differences between the claims involve merely obvious differences.

Applicant's arguments filed June 27, 2005 have been fully considered but they are not persuasive. The Sheldon balloons are made of Mylar (col. 8, lines 55-62) which is an inelastic material as admitted by Applicant in claim 21 of Bonutti (6,017,305). An balloon made of an inelastic material inherently expands to a predetermined shape, as opposed to an balloon made of an elastic material which expands to a shape based upon least resistance presented by the surrounding material. The balloon 57 of Sheldon will therefore expand both laterally as well as longitudinally to apply significant force

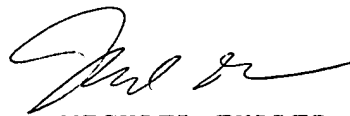
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in the lateral direction as well as the longitudinal direction and will therefore expand the vertebrae apart in the lateral direction, as least a slight amount. The amount of expansion has not been claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
12/8/05


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731